

ATTACHMENT 1 - 510K Summary

APR - 8 1997

510(k) Summary of Safety and Effectiveness Information MarDx ENA IgG ImmunoStripe Test System

K 964787

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and proposed 21 CFR Part 807.92.

Identification of Predicate Devices:

The MarDx ENA IgG ImmunoStripe Test System is substantially equivalent to the INOVA ENA EIA's for SSA, SSB, Sm, RNP, Jo-1, Scl-70 and the MarDx ENA EIA 6 in 1 Test System for the detection of immunoglobulin to SSA, SSB, Sm, RNP, Jo-1, Scl-70 in human serum.

Description of New Device:

The MarDx ENA IgG ImmunoStripe Test System is an enzyme-linked immunosorbent assay (EIA) for the detection of IgG to extractable nuclear antigens in human serum.

Statement of Intended Use:

The MarDx ENA IgG ImmunoStripe Test System is intended for use in testing human serum for the presence of human IgG to extractable nuclear antigens, as an aid in the diagnosis of autoimmune disease, such as systemic lupus erythematosus, Sjogren syndrome, scleroderma, and myositis.

Technological Characteristics of the Device:

The MarDx ENA IgG ImmunoStripe Test System is an enzyme linked immunosorbent assay to detect IgG, to SSA, SSB, Sm, RNP, Jo-1, Scl-70. Purified antigens are individually attached to specific locations on a solid phase support, nitrocellulose. Diluted test sera is added to a well containing the ImmunoStripe strip. If the antibodies are present that recognize an antigen, they will bind to the antigen present on the strip. After incubation the nitrocellulose strip is washed to remove unbound antibody. An enzyme labeled antihuman IgG is added to each strip. If antibody is present the conjugate will bind to the antibody attached to the specific antigens. The strip is washed to remove unbound conjugate and a substrate solution is then added. If the enzyme/antibody complex is present, the substrate will undergo a precipitation and color change. After an incubation period, the reaction is stopped and the presence of precipitated substrate is visualized at specific locations on the strip. The presence of a colored precipitation at pre-determined locations on the ImmunoStripe strip is an indirect measurement of specific antibody for SSA, SSB, Sm, RNP, Jo-1, Scl-70 in the patient specimen.

Description and Conclusions of the Clinical Studies.

The MarDx ENA IgG ImmunoStripe Test System is substantially equivalent to the INOVA ENA EIA's for SSA, SSB, Sm, RNP, Jo-1, Scl-70 and the MarDx ENA EIA 6 in 1 Test System for the detection of immunoglobulin to SSA, SSB, Sm, RNP, Jo-1, Scl-70 in human serum. Equivalence is demonstrated by the following comparative results:

Two hundred and sixty four sera were tested by EIA (INOVA ELISA for ENA antibodies), and the MarDx 6 in 1 ENA EIA, to determine the relative sensitivity and specificity of the MarDx ENA IgG Immunostripe test kit. One hundred and thirty-nine of the sera were from normal individuals which should not have antibodies to ENA antigens. One hundred and twenty five sera were from patients thought to have autoimmune disease and submitted as blind specimens for ENA antigen detection. The MarDx and INOVA assays were performed by the R&D laboratory at MarDx following manufacturer's package insert. Assay sensitivity ranged from 89 to 100%, specificity was 100%. The raw data from the study is prepared in Attachment 5. The data is summarized in Tables 1-11.

Table 1
Specificity of the MarDx ENA IgG Immunostripe Test System
relative to the INOVA EIA Test Systems

		INOVA EIA		
		Positive	Negative	Total
MarDx	Positive	0	0	0
Immunostripe				
	Negative	0	40	40
Total		0	40	40

Specificity (40/40) = 100%

Table 2
Specificity of the MarDx ENA IgG Immunostripe Test System
relative to the MarDx 6 in 1 ENA EIA Test System

		MarDx 6 in 1 ENA EIA		
		Positive	Negative	Total
MarDx	Positive	0	0	0
Immunostripe				
	Negative	0	139	139
Total		0	139	139

Specificity (139/139) = 100%

Table 3
Sensitivity of the MarDx ENA IgG Immunostripe Test System
relative to the INOVA SSA EIA Test System

Antigen: SSA		INOVA SSA EIA		
		Positive	Negative	Total
MarDx	Positive	35	0	35
Immunostripe				
	Negative	2	0	2
Total		37	0	37

SSA Sensitivity (35/37) = 95%

Table 4
Sensitivity of the MarDx ENA IgG Immunostripe Test System
relative to the INOVA SSB EIA Test System

Antigen: SSB		INOVA SSB EIA		
		Positive	Negative	Total
MarDx	Positive	16	0	16
Immunostripe				
	Negative	1	0	1
Total		17	0	17

SSB Sensitivity (16/17) = 94%

Table 5
Sensitivity of the MarDx ENA IgG Immunostripe Test System
relative to the INOVA Sm EIA Test System

Antigen: Sm		INOVA Sm EIA		
		Positive	Negative	Total
MarDx	Positive	20	1	21
Immunostripe				
	Negative	0	0	0
Total		20	1	21

Sm Sensitivity (20/20)= 100%

Table 6
Sensitivity of the MarDx ENA IgG Immunostripe Test System
relative to the INOVA RNP EIA Test System

Antigen: RNP		INOVA RNP EIA		
		Positive	Negative	Total
MarDx	Positive	33	0	33
Immunostripe				
	Negative	4	0	4
Total		37	0	37

RNP Sensitivity (33/37) = 89%

Table 7
Sensitivity of the MarDx ENA IgG Immunostripe Test System
relative to the INOVA Jo-1 EIA Test System

Antigen: Jo-1		INOVA Jo-1 EIA		
		Positive	Negative	Total
MarDx	Positive	2	0	2
Immunostripe				
	Negative	0	0	0
Total		2	0	2

Jo-1 Sensitivity (2/2)= 100%

Table 8
Sensitivity of the MarDx ENA IgG Immunostripe Test System
relative to the INOVA Scl-70 EIA Test System

Antigen: Scl-70		INOVA Scl-70		
		Positive	Negative	Total
MarDx	Positive	7	0	7
Immunostripe				
	Negative	0	0	0
Total		7	0	7

Scl-70 Sensitivity (7/7)= 100%

Table 9

INOVA SUMMARY
Sensitivity of the MarDx ENA IgG Immunostripe Test System
relative to the Six Combined Results from the INOVA ENA EIA Test Systems

Combined		INOVA ENA EIA		
		Positive	Negative	Total
MarDx	Positive	113	0	113
Immunostripe				
	Negative	7	0	7
Total		120	0	120

Sensitivity (113/120) = 94%

Table 10

**Sensitivity of the MarDx ENA IgG Immunostripe Test System
relative to the MarDx 6 in 1 ENA EIA Test System**

		MarDx ENA EIA		
		Positive	Negative	Total
MarDx	Positive	67	0	67
Immunostripe				
	Negative	2	0	2
Total		69	0	69

Sensitivity (67/69) = 97%

**Table 11
Summary Table For All Data**

MarDx		Reference Manufacturer	Number of Specimens	Reference	Sensitivity	Specificity
Immunostripe	vs	INOVA	35/37	SSA	95%	NA
Immunostripe	vs	INOVA	16/17	SSB	94%	NA
Immunostripe	vs	INOVA	20/20	Sm	100%	NA
Immunostripe	vs	INOVA	33/37	RNP	89%	NA
Immunostripe	vs	INOVA	2/2	Jo-1	100%	NA
Immunostripe	vs	INOVA	7/7	Scl-70	100%	NA
Immunostripe	vs	INOVA	40/40	Normals	NA	100%
Immunostripe	vs	MarDx	67/69	6 in 1	97%	NA
Immunostripe	vs	MarDx	139/139	Normals	NA	100%
Immunostripe	Combined Sensitivity and Specificity				95%	100%

Precision Study

The precision data is presented in Table 10 for 7 sera (Jo-1, 3 sera) assayed 8 times each on three different assays. The data indicates that the MarDx ENA Immunostripe has a high degree of precision both within and between assays.

Table 12

Sample		Assay 1		Assay 2		Assay 3	
		Ratio	Percent				
1	SSA	7/7	100%	7/7	100%	7/7	100%
2	SSB	7/7	100%	7/7	100%	7/7	100%
3	Sm	7/7	100%	7/7	100%	7/7	100%
4	RNP	7/7	100%	7/7	100%	7/7	100%
5	Jo-1	3/3	100%	3/3	100%	3/3	100%
6	Scl-70	7/7	100%	7/7	100%	7/7	100%
7	Normal	7/7	100%	7/7	100%	7/7	100%
TOTALS		45/45	100%	45/45	100%	45/45	100%

Precision = 100%

Cross-Reactivity Study

The cross-reactivity data is presented in Table 11 for 7 sera containing dsDNA antibodies. The data indicates that the MarDx ENA Immunostripe does not cross-react with dsDNA.

Table 13

Sample	Result
1	Neg
2	Neg
3	Neg
4	Neg
5	Neg
6	Neg
7	Neg

Cross Reactivity to dsDNA = 0%